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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
LEE, JAE W	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,795	SINCLAIR ET AL.	
	Examiner	Art Unit	
	JAE W. LEE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/23/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5 and 7-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5 and 7-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application status

In response to the previous Office action, a non-Final rejection (mailed on 03/31/2008), Applicants filed a response and amendment received on 07/23/2008. Said amendment canceled Claims 2-4, 6, 28 and 34, and amended Claims 1, 5, 8, 8, 11, 17, 24, 25, 27, 29, 30, 31 and 33. Thus, Claims 1, 5 and 7-25 are at issue and present for examination.

Applicants' arguments filed on 07/23/2008, have been fully considered, and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

It is noted by the Examiner that Claims 26-33 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention in the previous Office actions, a non-Final rejection (mailed on 3/31/08).

Election

The Examiner has fully considered Applicants' argument regarding the unity of invention. Even if one argues that Narayana et al. do not teach the special technical

feature that unites the inventions in Groups I-IV, the Examiner finds that such argument does not overcome the previous restriction requirement for the following reasons.

The elected invention of Group I does not have unity of invention with the method of Group II according to 37 CFR 1.475(b)(c) since Group I already contains one method of use/manufacture, and the method of Group II is drawn to an additional method of use of the elected invention of Group I.

Furthermore, according to PCT Rule 13.2 unity of invention exist only when there is a shared same or corresponding special technical feature among the claimed inventions. The protein lattice of Group I, the polynucleotide of Group II, the antibody of Group III, and the compound of Group IV lack a shared same or corresponding special technical feature. The special technical feature of Group I is a polypeptide which comprises the polypeptide of SEQ ID NO: 2 or an analogue/derivative thereof, The special technical feature of Group II is a nucleic acid which encodes a polypeptide having at least 95% sequence identity to the polypeptide of SEQ ID NO: 2. The special technical feature of Group III is a protein which has a different structure and function from that of Group I and binds specifically to a polypeptide having at least 95% sequence identity to the polypeptide of SEQ ID NO: 2. The special technical feature of Group IV is a structurally undefined compound which stimulates, enhances, antagonizes or inhibits the polypeptide of Group I. Therefore, none of these special technical features is shared by or corresponds to any of the inventions of Groups I-IV.

Drawings

The previous objection of drawings for missing "Figure 2" label is withdrawn by virtue of Applicants' amendment.

Objections to the Specification

The previous objection of the specification for the inclusion of the inappropriate notation of an Internet address is withdrawn by virtue of Applicants' amendment.

The previous objection of the abstract for containing 266 words, is withdrawn by virtue of Applicants' amendment which shortened it to 148 words.

The previous objection for containing nucleic acid sequences on pg. 21 and failing to comply with the sequence rules as set forth in 37 CFR 1.821(a)(1) and (a)(2) is withdrawn by virtue of Applicants' amendment.

Claim Objections

The previous objection of Claims 5, 6 and 16 for the recitation of "[[any of claims…]]" is withdrawn by virtue of Applicants' amendment.

Claim 1 is objected to because of the following informalities:

Claim 1 is objected to for the recitation of "protein protomers which each comprise" which can be substantially improved with respect to form. The Examiner suggests replacing the noted phrase with ---protein protomers wherein each protein protomer comprises---.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of Claim 1-25 for the recitation of the word "respective" in many different phrases, is withdrawn by virtue of Applicants' Amendment which deleted all instances of the noted term except for claim 18. It is noted that the use of "respective" in claim 18 is not indefinite.

Claims 1, 5 and 7-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, 5 and 7-25 are unclear and confusing in the recitation of the phrase, "a set of rotational symmetry axes extending in three dimensions". The reason is that the noted phrase can be interpreted in two different ways. It can be interpreted as "a set of

rotational symmetry axes extending in the three dimensional space", or "a set of rotational symmetry axes extending in 3 different directions". In the interest of advancing prosecution, the noted phrase is not given any patentable weight.

Claim 1, 5 and 7-25 are unclear and confusing in the recitation of the words "first" and/or "further" in many different phrases:

Claims 1, 13 and 18: "first [or further] oligomer assembly," and "first or [further] monomers;"

Claims 10, 11, 14 and 19: "first oligomer assembly;"

Claim 8: "first and further monomers," "first oligomer assembly," and "first monomers."

It is unclear and confusing as to how these "first oligomer assembly" and "first monomers" are related to any other "further" oligomer assemblies and monomers that make them "first." Although Applicants argue that "first" is used to distinguish from "further" monomers/oligomer assembly, in view of the definition disclosed in Webster's dictionary:

Further

Fur"ther\, a. compar. [Positive wanting; superl. Furthest.]
1. More remote; at a greater distance; more in advance; farther; as, the further end of the field. See Farther.
2. Beyond; additional; as, a further reason for this opinion; nothing further to suggest.
Note: The forms further and farther are in general not differentiated by writers, but further is preferred by many when application to quantity or degree is implied.

Webster's Revised Unabridged Dictionary, © 1996, 1998 MICRA, Inc.

"further" can be interpreted as "additional", and such interpretation fails to distinguish "first" from "additional" monomers/oligomer assemblies. Therefore, for the reasons provided herein and in the previous office action, the use of "first" and "further" in these claims are unclear and indefinite. It is noted by the Examiner that "further" monomers/oligomer assemblies are not defined in the specification. In the interest of advancing prosecution, the term "first" is not given any patentable weight, and the term "further" is interpreted as "additional".

Claim 1, 5 and 7-25 are unclear and confusing in the recitation of the phrase, "A protein lattice having ... [1] the repeating unit comprising *protein protomers ...*, [2] wherein the repeating unit comprises *protomers comprising at least a first monomer which is a monomer of a first oligomer assembly which has a set of rotational symmetry axes extending in three dimensions; and at least a further monomer fused to said first monomer which further monomer is a monomer of a further oligomer assembly, each further oligomer assembly having a rotational symmetry axis of the same order as one of the set of rotational symmetry axes of the first oligomer assembly and being aligned with the one of the set of rotational symmetry axes of the first oligomer assembly*" (italicized for added emphasis). It is unclear with regard to whether Applicants are claiming a protein lattice having (A) [1] and [2], (B) [1] or [2], and (C) [1] further limited by the limitations of [2]. Since the repeating unit of [2] comprises "*protomers* comprising at least a first monomer which is a monomer of a first oligomer assembly which is has a set of rotational symmetry axes extending in three dimensions; and at least a further monomer fused to said first monomer which further monomer is a monomer of a further

oligomer assembly, each further oligomer assembly having a rotational symmetry axis of the same order as one of the set of rotational symmetry axes of the first oligomer assembly and being aligned with the one of the set of rotational symmetry axes of the first oligomer assembly" and NOT the "*protein protomers*" as recited in [1], it is unclear and indefinite as to what the protein lattice comprises. In the interest of advancing prosecution, the phrase, "wherein the repeating unit comprises protomers...oligomer assembly" is not given any patentable weight.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5 and 7-25 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 1-25. In response to this rejection, Applicants have cancelled claims 2-4 and 6, amended claims 1, 5, 8, 9, 11, 16, 17, 24 and 25, and traverse the rejection as it applies to the newly amended claims.

Applicants point out that even though at the time the instant application was filed, laboratory production of a protein lattice in accordance with the present invention had only been demonstrated for the quoted example of human HFH and E. coli PurE, this is sufficient to support the scope of the claims, because of the special nature of the present invention. Applicants argue that the present invention differs from a typical protein invention in that it is not concerned directly with the chemical and biochemical properties of the protein as such. Rather, the present invention is concerned with a principle based on the symmetry of the quaternary structure of the proteins. One of the contributions provided by the present invention is that the internal symmetries of an oligomer assembly can be used to design and build a new class of protein lattices. Applicants allege that as the contribution is made at this level of generality, it is appropriate that the scope of the claims is made at this level of generality. In some ways, this particular invention is more clearly analogous to an invention in the field of mechanical engineering, rather than an invention in the field of biotechnology. The specification contains a very detailed disclosure of the principles of how monomers of oligomer assemblies having particular symmetries can be chosen to produce a protomer which will assemble into a lattice. This is set out as follows. (a) Page 4, lines 8-19 explains that protein lattices can be designed by selecting oligomers having appropriate symmetries. (b) Page 4, line 26 through page 8, line 3 describes the principles by which the symmetries of the lattice derives from the symmetry axes of the oligomer assemblies. (c) Page 10, line 4 through page 16, line 28 describes numerous specific examples of the combinations of symmetries of the oligomer assemblies which

allow a protein lattice to form, for example as enumerated in Tables 1 and 2. (d) As the invention is based on the principle that oligomer assemblies of appropriate symmetries can be used to build a protein lattice, the actual identity of the individual proteins is less important than their symmetry. Page 4, lines 13-19 explains that the symmetries of oligomer assemblies are generally known. Furthermore, Applicants point out that Table 3 gives examples of some common proteins of different symmetry groups which are mentioned as the examples in Tables 1 and 2. In other words, protomers having appropriate symmetries can be selected by choosing symmetries of each oligomer assembly from Tables 1 and 2 and then selecting specific proteins having those symmetries from Table 3. Applicants respectfully submit that the parts of the application (a)-(d) set out above which clearly allow the skilled person to predict structures having the required symmetries to form a lattice and a contribution provided by the present invention is that certain symmetries allow a protein lattice to form, adequately meet the written description requirement. Thus the "common characteristics" that need to be identified in the case of the present invention are the symmetries of the resultant protein lattice, which again are taught by the parts of the application (a)-(d) set out above. Applicants further argue that uses of the claimed invention, i.e., catalyzing biotransformations, data storage, display, charge separation, nanowire, motor, mould and X-ray crystallography, all derive from the symmetry and structure of the protein lattice which is described as set out above. Thus, it is in fact the case that the relevant properties can be recognized. In addition, with the exception of X-ray crystallography, none of the above mentioned uses are set forth in the instant claims. With respect to X-

ray crystallography, the specification has detailed description of how the protein lattice of the present invention can be used in X-ray crystallography, e.g., at page 24, line 7 through page 8, line 1. In summary, pending Claims 1, 5 and 7-25 meet the written description requirement under 35 U.S.C. § 112, first paragraph.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. First, claims are drawn to a genus of protein lattices having a regular structure with a repeating unit repeating in three dimensions, the repeating unit comprising any protein protomers wherein each protein protomer comprises at least two monomers fused together, the monomers each being any monomers of an oligomer assembly into which the monomers are assembled for assembly of the protomers into the lattice (see 112 2nd paragraph rejections above for the claim interpretation). As noted previously, the genus of protein protomers and fused monomers which can be assembled into a lattice encompasses widely variant polypeptide and monomers essentially having any structure. In addition, the specification lacks support for the genus of any protein protomers and fused monomers and how such genus of widely variant structures correlates with a desired function/activity. Even if one argues that the present invention differs from a typical protein invention in that it is not concerned directly with the chemical and biochemical properties of the protein as such, but rather, concerned with a principle based on the symmetry of the quaternary structure of the proteins, it is noted that the specification lacks disclosure of the representative species of the recited genus because the specification only discloses two proteins human HFH and E. coli PurE which can be

fused together to form a protein lattice, wherein said proteins have a specific rotational axes based on the octahedral point group and dihedral D4 point group, respectively. In light of the fact that it is highly unpredictable for one of skill in the art to identify 3-D structure and rotational axes that may exist in a protein from its amino acid sequence, especially when two proteins that are fused together which may significantly alter the 3-D conformation of each of the two proteins, one of skill in the art would not have recognized that Applicants were in possession of a protein lattice having any protein protomers wherein each protein protomer comprises any two monomers fused together. In support of the Examiner's position, Applicants have stated that "at the time the instant application was filed, laboratory production of a protein lattice in accordance with the present invention had only been demonstrated for the quoted example of human HFH and E. coli PurE" on page 13, last paragraph in the remarks filed on 07/23/2008.

Taken together, the limited disclosure in the specification, i.e., a single protein lattice which can be made using human HFH and E. coli PurE, wherein said proteins have a specific rotational axes based on the octahedral point group and dihedral D4 point group, respectively, and the lack of any experimental data to support the notion that all possible combinations of all proteins/monomers having any set of rotational symmetry axes can be fused together to form a protein lattice, one of skill in the art would not have recognized that the genus of protein lattices, encompassing widely variant species having essentially any structure, can be used in extremely diverse applications as listed in pg. 25, i.e., catalyzing biotransformations, data storage, display, charge separation, nanowire, motor, mould and X-ray crystallography. Please refer to

the M.P.E.P. section 2163 [R-5] under II, A, 3, (a), (ii) for more details with respect to sufficient number of representative species that should be disclosed to describe a widely variant genus.

Given the lack of additional representative species of the a genus of protein lattices having a regular structure with a repeating unit repeating in three dimensions, the repeating unit comprising any protein protomers wherein each protein protomer comprises at least two monomers fused together, the monomers each being any monomers of an oligomer assembly into which the monomers are assembled for assembly of the protomers into the lattice, as encompassed by the claim, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

For the reasons provided herein and in the previous office action, the rejection under this statute is maintained.

Claims 1, 5 and 7-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because the specification, while being enabling for a protein lattice comprising a fusion protein comprising the human ferritin

heavy chain (HFH) and the E. coli PurE encoded by human HFH and E. coli PurE genes amplified by PCR from human cDNA and E. coli gDNA, respectively using primers 5'-CCT TAG TCG AAT TCA TGA CGA CCG CGT CCA CC-3' and 5'-GGG AAA TTA GCC CTC GAG TTA GCT TTC ATT ATC-3' for the ferritin gene, and primers 5'-GTT TTA AGA CCC ATG GCT TCC CGC AAT AAT CCG-3' and 5'-CGC AAA CCT GGA TCC TGC CGC ACC TCG CGG-3', for the PurE gene, as shown in Figure 1, does not reasonably provide enablement for any protein lattice having a regular structure with a repeating unit repeating in three dimensions, the repeating unit comprising any protein protomers wherein each protein protomer comprises at least two monomers fused together, the monomers each being any monomers of an oligomer assembly into which the monomers are assembled for assembly of the protomers into the lattice as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 1-25. In response to this rejection, Applicants have cancelled claims 2-4 and 6, amended claims 1, 5, 8, 9, 11, 16, 17, 24 and 25, and traverse the rejection as it applies to the newly amended claims.

Applicants argue that the techniques applied to make the protomers and then assemble them are routine in the art by the use of a protomer which has appropriate symmetries, to build into a protein lattice. The form and production of the protomers is described at page 8, line 4 through page 10, line 3 and at page 19, line 2 through page

21, line 8. All of these techniques are routine. Essentially these techniques simply require production of a fusion proteins which was commonplace at the time the instant application was filed. The form and production of the protomers are also taught in WO 00/68248, filed May 8, 2000 and published November 16, 2000, the entire teachings of which are incorporated by reference in the present application. Similarly, the assembly process is described on page 21, lines 9-23. Again these techniques are routine. Essentially, it is required only that the protomers are mixed in conditions allowing assembly of the oligomer assemblies (albeit in two stages in the case of heterologous protomers), which was straightforward at the time the instant application was filed. Suitable conditions for the assembly process are also disclosed in WO 00/68248, the entire teachings of which are incorporated by reference in the present invention. It is not alleged that every protomer having the requisite symmetries will form a lattice. However, the present application explains the factors involved in the selection of proteins to maximize the chances of assembly of a lattice, for example, at page 8, line 31 through page 10, line 3. Applicants attach hereto as Exhibit A, a copy of a document filed at the European Patent Office on August 16, 2006 in connection with European Patent Application No. 03753741.2 which corresponds to the instant U.S. application. The document is an annex to Response to the Communication of February 10, 2006 from the European Patent Office. The document describes an additional experimentally demonstrated 3D regular protein lattice in accordance with the present invention. This example of post-filing success is strong evidence that the instant application is enabling. Applicants allege that it is straightforward to conceive of and implement protein lattices

comprising protomers other than human HFH and E. coli PurE without undue experimentation.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. First, the scope of the claims encompasses any protein lattice having a regular structure with a repeating unit repeating in three dimensions, the repeating unit comprising any protein protomers wherein each protein protomer comprises at least two monomers fused together, the monomers each being any monomers of an oligomer assembly into which the monomers are assembled for assembly of the protomers into the lattice (see 112 2nd paragraph rejections above for the claim interpretation). In other words, the scope of the claims encompasses any protein protomers and any fused monomers which can be assembled into a lattice which include widely variant polypeptides and monomers essentially having any structure. In addition, the specification lacks disclosure of how any protein protomers and any fused monomers having any structure correlate with a desired function/activity. Given the limited disclosure provided by the specification, i.e., human HFH and E. coli PurE which can be fused together to form a protein lattice, wherein said proteins have a specific rotational axes based on the octahedral point group and dihedral D4 point group, respectively, the scope of the claimed invention is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of different proteins protomers and monomers.

Even if one argues that the present invention differs from a typical protein invention in that it is not concerned directly with the chemical and biochemical

properties of the protein as such, but rather, concerned with a principle based on the symmetry of the quaternary structure of the proteins, in light of the fact that [1] it is highly unpredictable for one of skill in the art to identify 3-D structure and rotational axes that may exist in a protein from its amino acid sequence, especially when two proteins that are fused together which may significantly alter the 3-D conformation of each of the two proteins, [2] the specification lacks of any guidance and experimental data with respect to how all possible combinations of all protein protomers/fused monomers, optionally having any set of rotational symmetry axes can be fused together to form a protein lattice, and [3] Applicants' admission that "at the time the instant application was filed, laboratory production of a protein lattice in accordance with the present invention had only been demonstrated for the quoted example of human HFH and E. coli PurE" (see on page 13, last paragraph in the remarks filed on 07/23/2008), it would require one of skill in the art undue experimentation to make and use the claimed invention.

It is noted by the Examiner that Exhibit A only discloses an additional example of a protein lattice, i.e., crysalins, comprising a small heat shock protein and streptavidin/streptag assembly having specific symmetry, which was obtained after filing of the instant application. However, this information does not enable one of skill in the art to make and use the scope of the invention as claimed because one would be left with testing all possible combinations of all protein protomers/fused monomers, optionally having any set of rotational symmetry axes, and determining which of these combinations can be fused together or used together to form a protein lattice with the exception of the single example that is provided by the specification, i.e., human HFH

and E. coli PurE which can be fused together to form a protein lattice, wherein said proteins have a specific rotational axes based on the octahedral point group and dihedral D4 point group, respectively.

Although the method of making fusion proteins was known in the art at the time the instant application was filed, it would require undue experimentation for one of skill in the art to test which combinations of all possible protein protomers/fused monomers having any structure, optionally having any symmetry, can be used to assemble protein lattice out of an infinite number of possible combinations, and identify those that can be used in applications as intended by Applicants, i.e., catalyzing biotransformations, data storage, display, charge separation, nanowire, motor, mould and X-ray crystallography (see pg. 25).

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any protein lattice having the desired biological characteristics/functions is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

For the reasons provided herein and in the previous office action, the rejection under this statute is maintained.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 and 7-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Padilla et al. (Nanohedra: Using symmetry to design self assembling protein cages, layers, crystals, and filaments, PNAS, 2001, Vol. 98, No. 5, pg. 2217–2221, see IDS), in view of the evidentiary reference Hestenes (Retrieved from the Internet at <http://modelingnts.la.asu.edu/pdf/crystalsymmetry.pdf>, [Retrieved on 3/18/08]).

The rejection was stated in the previous office action as it applied to previous claims 1-25. In response to this rejection, Applicants have cancelled claims 2-4 and 6, amended claims 1, 5, 8, 9, 11, 16, 17, 24 and 25, and traverse the rejection as it applies to the newly amended claims.

Applicants argue that Padilla et al. does not teach that the protomers each comprise a first monomer which is "a monomer of a first oligomer assembly which has a set of rotational symmetry axes extending in three dimensions" (emphasis added), because the monomers of Padilla et al. are dimers and trimers each having a single rotational symmetry axis, i.e., of order two or three. Applicants further argue that Padilla et al. does not teach that the protomers comprise at least a further monomer which is a "monomer of a further oligomer assembly, each further oligomer assembly

having a rotational symmetry axis of the same order as one of the set of rotational symmetry axes of the first oligomer assembly and being aligned with the one of the set of rotational symmetry axes of the first oligomer assembly."

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Claims are drawn to a protein lattice having a regular structure with a repeating unit repeating in three dimensions, the repeating unit comprising protein protomers wherein each protein protomer comprises at least two monomers fused together, the monomers each being monomers of an oligomer assembly into which the monomers are assembled for assembly of the protomers into the lattice (see 112 2nd paragraph rejections above for the claim interpretation). Due to the indefiniteness of the claim language as explained above, the claims as amended are not limited to a protein lattice comprising a first or further monomer having any set of rotational symmetry axes (see above 112 2nd paragraph rejection). However, even if the monomer was limited to those having a set of rotational symmetry axes, the bromoperoxidase taught by Padilla et al. which is the "1bro" in the PDB database (see pg. 3218, left column, lines 4-5), has the $P2_13$ space group identified in its 3-D structure obtained by the X-ray crystallography, which has more than 1 rotational symmetry axes. As previously noted, the monomers, i.e., bromoperoxidase and M1 matrix protein of influenza virus connected, taught by Padilla et la. are linked by a nine-residue helical linker, thereby anticipating claim 7. For the reasons provided herein and in the previous office action, Padilla et al. still anticipate the claimed invention, and the rejection under this statute is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5 and 7-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 and 33 of copending Application No. 11/807922.

The rejection was stated in the previous office action as it applied to previous claims 1-25. In response to this rejection, Applicants have cancelled claims 2-4 and 6, amended claims 1, 5, 8, 9, 11, 16, 17, 24 and 25, and do not traverse the rejection as it applies to the newly amended claims. Applicants note that upon allowance, Applicants will address any double patenting rejections in the remarks filed on 07/23/2008.

Conclusion

Claims 1, 5, and 7-25 are rejected for the reasons as stated above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/
Examiner, Art Unit 1656

/Rebecca E. Prouty/
Primary Examiner,
Art Unit 1652